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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SINGH, SATYENDRA K	

ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,503	FISCHER, DAN E.	
	Examiner	Art Unit	
	Satyendra K. Singh	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10,14,15 and 28-33* is/are pending in the application.

4a) Of the above claim(s) *11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10,14,15 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 16th 2007 has been entered.

Claims 11-13 (group II) remain withdrawn from further consideration.

Claims 1-4, 6-10, 14, 15 and 28-33 (as currently amended) are examined on their merits in this office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-4, 6-10, 14, 15 and 28-33 (as currently amended) are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al (US 4,863,472; [D]) taken with Silverberg (US 4,755,184; [E]), Levy (US 5,292,253; [A]) and Vyakarnam et al (US 6,306,424 B1; [F]), and further in view of Kenyon et al (US 2,423,707; [A]).

Claims are generally directed to **an implant device** comprising a dry covering comprised of "a water absorbing gelatinizable material" that defines an enclosed space (and which becomes sticky and gelatinous upon contact with water), a "bone growth promoting material", disposed within the enclosed space defined by the dry covering (as recited in claim 1; as amended), wherein the dry covering forms an outer cover of the implant device so as to encapsulate the bone growth promoting material within the enclosed space (see instant claims 1-4, 6-10, 14, and 15); and wherein the implant device comprises the bone growth promoting material in granular or powder form, and a thickener dispersed among said bone growth promoting material (see specific recitations of claims 28-33).

Tormala et al [D] disclose an implant device comprising "water absorbing gelatinizable material" (a supporting structure suitable to work as a covering/encasing made of materials such as polyglycolide, **cellulose derivatives** or cross-linked **collagen** derivatives such as cat gut/**Katgut**; see Tormala et al, abstract; figures 1-2; columns 3-4; and column 4, lines 17-25, in particular) and a "bone growth promoting material" contained within said gelatinizable material (see Tormala et al, abstract and claims, in particular), wherein the water absorbing gelatinizable material is resorbable or non-resorbable, wherein bone growth promoting material is as specifically recited in instant claim 5 (such as synthetic ceramic powders, or **hydroxyapatite** powder; see column 8, example 2, in particular), wherein the implant device has an elongated sausage-like or pillow like configuration (in the absence of any defined structural features/parameters in the claims for such "sausage-like" or "pillow-like configuration;

see Tormala et al, figures 1-3 and column 5, 3rd paragraph, in particular), and a method of promoting bone growth comprising providing said implant device of claim 1, and placing the implant device adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. alveolar ridge augmentation, and gingival repair; see Tormala et al, columns 5-6, in particular). In addition, Tormala et al disclose the fact that one can use or admix resorbable fibers, or polymer to bind (to work as a glue, i.e. used as a **thickener** that can form viscous gel upon contact with water) the bone graft particles together, if used as an additional inner resorbable supporting structure of the powder phase (see column 3, lines 1-2; column 4, last paragraph; and claim 9, in particular). Also disclosed in Tormala et al is the fact that the supporting structure (i.e. the covering) can be made of any shape or size (such as a bag or a flat tube; see abstract, column 6, lines 57-64, in particular) and the covering can be constructed in the form of a **woven or knitted** fibers (see column 5, lines 36-38, and claim 10, in particular).

Silverberg [E] discloses an implant device comprising "water absorbing gelatinizable material" (suitable to work as a covering material such as **a casing** made from polyglycolide in the form of a mesh, or **collagen or cellulose**; see abstract, summary of the invention, column 3, lines 31-55, and claims, in particular) and a "bone growth promoting material" contained within said gelatinizable material (such as hydroxyapatite; see examples, column 4-5, in particular), wherein the water absorbing gelatinizable material is resorbable, wherein bone growth promoting material is hydroxyapatite powder, wherein the implant device has **an elongated sausage-like or**

pillow like configuration (see figure1, in particular) and is gas sterilized prior to surgical applications (see column 5, 1st paragraph, in particular); and a method of promoting bone growth comprising providing said implant device of claim 1, and placing the implant device adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. alveolar ridge augmentation, and gingival repair; see Silverberg, column 4 and figure 3-5, in particular).

However, the inventions of Silverberg or Tormala et al do not explicitly teach (although, suggest the generic materials such as collagen and cellulose, and derivatives thereof; see discussions above) the "dry covering" to be made of a water absorbing material that becomes sticky and gelatinouos upon contact with water (see also recitation of instant claim 2).

Kenyon et al [A] disclose a **gelatinizable gauze** (i.e. a surgical fabric or sponge made of **oxidized cellulose**; see columns 1-2, and claims in particular) to be used as a dressing material on wounds, cuts and the like, wherein the gauze can be resorbable (see column 1, last paragraph, in particular) *in vivo*, or non-resorbable (depending on the amount or extent of oxidization using NO_2 and a halogenated hydrocarbon; see column 2, 2nd paragraph, and examples 1 and 2, in particular), and thus, can be used as a hemostat or as a dressing (in woven or knitted forms; see figures 1-2) for the treatment of the wound.

Therefore, it would have been obvious to a person of ordinary skill in the clinical art to modify the inventions of Tormala et al or Silverberg such that the covering used is made of a water absorbable gelatinizable material such as oxidized cellulose (i.e. a gelatinizable gauze made of oxidized cellulose) which is explicitly taught by Kenyon et al for the benefits of having both resorbable and/or non-resorbable properties of the

oxidized cellulose material used in the form of a woven or knitted material. Thus, an artisan of ordinary skill in the medical art would have had a clear motivation and a reasonable expectation of success in substituting the "dry covering" disclosed by Tormala et al or Silverberg with the material (i.e. a functional equivalent, such as cellulose derivatives including oxidized cellulose that are known to be gelatinizable upon contact with water or other aqueous materials such as body fluids, and are known to be made in bio-resorbable as well as non-bioresorbable forms) explicitly taught by Kenyon et al for the treatment of wounds that produce bleeding (such as during the removal and filling of tooth, etc.).

However, an implant device further comprising an adhesive such as **fibrin powder** (see instant claims 9-10); or a implant device, which is stored within **moisture-resistant packaging** is not explicitly disclosed by the referenced inventions of Silverberg, Tormala et al, and Kenyon et al.7

Levy [A] explicitly discloses the use of **fibrin** with or without collagen (see column 3, lines 24-29, and claims, in particular) to form a protein gel that can be combined with calcium-containing materials such as hydroxyapatite and/or calcium phosphate to prepare an implant used for filling the void or defects for the repair of tooth and bone tissues.

Vyakarnam et al [F] disclose the routine practice of packaging implant materials after sterilization in an appropriate sterilized, **moisture-resistant package** for shipment and use in hospitals and other health care facilities (see column 19, 3rd paragraph, in particular).

Therefore, given the detailed disclosures of the components and the structure of the implant device (as claimed in the instant application) in the above cited prior art references, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the implant device taught by Tormala et al (taken with the disclosure of Silverberg and Kenyon et al) such that it further comprises an adhesive such as fibrin, and is stored within a moisture-resistant packaging as explicitly suggested and demonstrated by the disclosures of Levy and Vyakarnam et al with a reasonable expectation of success in order to provide a gelling component or a glue in the composition as well as to avoid contamination of the implant device during storage (both the limitations are deemed to be routinely practiced in the implantation art).

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the clinical art at the time the claimed invention was made.

As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Response to Applicant's Arguments

Applicant's arguments (and exhibits A-E) filed with the office on November 16th 2007 (as they pertain to the prior art rejection of record) have been fully considered but they are not persuasive for the following reasons of record.

Applicant's arguments are mainly focused on the point that the cited prior art references do not explicitly disclose "dry covering" that is comprised of materials "which become sticky and gelatinous upon contact with water" (see remarks, pages 7-10). In response, it is noted that Tormala et al disclose and explicitly suggest the use of cellulose, chitin, gelatin and collagen derivatives (see Tormala et al, column 4) for the tube or bag-like porous, supporting structure (i.e. an encasing for the graft material such as hydroxyapatite). In addition, Silverberg also suggests the use of bovine collagen or cellulosic materials (see column 3, in particular) for making and using the porous encasing for the prosthetic bone filling material. As evidenced by the fact that variety of cellulose derivatives (including gelatinizable gauze or dressing materials) have been known in the clinical art (i.e. used for making a variety of wound dressings), for example, the disclosure of Kenyon et al attests to the fact that both resorbable as well as non-resorbable cellulose derivatives (made from oxidized cellulose, that can become sticky and gelatinous upon contact with water; see Kenyon et al, discussion above) have been well known in the clinical art, and in turn would have been obvious for an artisan of ordinary skill to substitute as an encasing material, depending on the need or type of treatment procedure.

The exhibits A-E filed by applicant are fully considered, however, since the claim does not exclude possible conditions wherein the cited polymeric materials such as cellulose, collagen or derivatives thereof, can be made to behave "sticky and gelatinous upon contact with water", the claimed limitations as presented by applicant is deemed to be fully met, especially as supported by the disclosure of Kenyon et al, as discussed above.

The argument that "*the polymeric materials in Tormala et al. are expressly described as being "resorbable". It would be contrary to Tormala et al. to provide a material as a covering that is "non-resorbable" as required by claim 4*", is fully considered but is not found to be persuasive because as evidenced by the teachings of Kenyon et al, it is clear that the cited prior art references of Tormala et al taken with Silverberg (as discussed above) provide the basis of substituting functional equivalents (i.e. encasing made from cellulose derivatives, such as oxidized cellulose derivative that can be suitable for both resorbable and non-resorbable purposes in the clinical art) that have been well known in the art. Since, the claims are not limited by any definition for the terms "resorbable" or "non-resorbable" in the instant specification (neither do they require a time frame for the materials to be resorbed *in vivo*), and since all the components of the "implant device" is known and explicitly suggested in the prior art, the obviousness rejection of record over the cited prior art references (as discussed above) is deemed proper.

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Satyendra K. Singh
Patent Examiner
Art unit 1657

IRENE MARX
PRIMARY EXAMINER